**EAST CAROLINA UNIVERSITY INFORMATION SHEET**

**FOR THE USE OF A SPONSOR’S INFORMED CONSENT DOCUMENT TEMPLATE**

If you have been provided with an informed consent template by a study sponsor which contains the [Essential elements of informed consent and, if necessary, the Additional elements of informed consent and/or FDA required ClinicalTrials.gov language](https://rede.ecu.edu/umcirb/wp-content/pv-uploads/sites/457/2021/12/CONSENT-ELEMENTS-1-21-2019_reviewed-12-6-21.pdf), you may use that template for your study consent document. HOWEVER, you must insert certain institutionally required language into the consent document in order for the IRB to approve the document for use. If the human research study does not involve ECU, reference to ECU requirements/contacts should not be included and you should verify that site-specific appropriate language is included instead. The required language that must be inserted into the sponsor’s template is outlined below.

**REQUIRED LANGUAGE:**

1. **The following identifying information must be present at the top of the first page of the consent document.**

Title of Research Study:

Sponsor/Funding Source:

Sponsor Protocol #:

Principal Investigator:

Institution/Department or Division***(As Applicable)***:

Address:

Telephone#:

Study Coordinator ***(If Applicable)***:

Telephone #:

1. **Patient Identification as a Research Participant**

For all study consents where the target population consists of patients a name and date of birth line must be inserted on the first page of the consent document and the participant must be told that a copy of the consent document will be placed in their medical record. You may cut and paste the required language from the block below.

Participant Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Please PRINT clearly**

Should you agree to participate in this research, a copy of this document will be included in your medical record.

1. **Research Injury Language**

The consent document must address the issue of possible injury as a result of taking part in more than minimal risk research. **For sponsored studies, it is the PI’s responsibility, when drafting the informed consent, to ensure the following information mirrors the language agreed upon in the approved contract document.** You may cut and paste the appropriate language from the block below.

***For industry-sponsored studies, include the following statement:***

If you believe you have been hurt or if you get sick because of something that is done during the study, you should call ***[Principal Investigator or medical supervisor’s name]*** at ***[insert telephone number]*** immediately. There are procedures in place to help attend to your injuries or provide care for you.  The sponsor of this study has some funds available to pay for care for injuries resulting directly from being in this study, while ECU does not.

If your illness or injury is the result of the study drug or any procedure required by the study that you would not have undergone if you had not participated in the study, the sponsor will pay medical expenses for reasonable and necessary treatment. The sponsor is not responsible for expenses that are due to (a) the failure of the study team to provide appropriate care, follow expected standards, or act responsibly, (b) underlying illness or pre-existing medical condition, unless the underlying illness or medical condition is made worse by your participation in the study, (c) procedures which would have been performed even if you were not participating in the study, and (d) failure of the study team to follow the study plan or sponsor’s instructions regarding the study drug.

***(If the sponsor has indicated they will pay for research related injury, the following paragraph should be added to the consent)*** If you are injured as a result of taking part in this study, the sponsor will pay for the costs associated with your care. However, because the sponsor is required by federal law to report that payment to the Center for Medicare and Medicaid Services, ECU will be asked to release your identifiable information (including your social security number) to the study sponsor. The sponsor will only use your information to meet federal reporting obligations and to make any payments to you. ECU will request your authorization before it releases information to the sponsor. You have the right to decline this authorization. If you decline, you will not be able to receive payment to cover the costs of medical treatment of your research related injuries and therefore you will be responsible for those costs.

**OR**

***For unfunded, federal, state, or foundation/non-profit studies, include the following statement:***

If you believe you have been hurt or if you get sick because of something that is done during the study, you should call ***[Principal Investigator or medical supervisor’s name]*** at ***[insert telephone number]*** immediately. There are procedures in place to help attend to your injuries or provide care for you. Costs associated with this care will be billed in the ordinary manner, to you or your insurance company. However, some insurance companies will not pay bills that are related to research costs. You should check with your insurance about this. Medical costs that result from research-related harm may also not qualify for payments through Medicare, or Medicaid. You should talk to the Principal Investigator about this, if you have concerns.

1. **Local Contact Information**

The consent document must contain local contact information should the participant have any questions about the research or his/her rights as a research participant. You may cut and paste the required applicable language from one of the blocks below.

If HIPAA authorization **IS NOT INCLUDED** in the informed consent document, the following language should be used:

If you have questions about your rights as someone taking part in research, you may call the ECU University and Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (days). ***[for research studies conducted through ECU Health also add “You may also contact the ECU Health Center for Research and Grants at research@ecuhealth.org]*** If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914 ***[for research studies conducted through ECU Health add…“and the ECU Health Risk Management Office at 252-413-4473”]***.

If HIPAA authorization **IS** **INCLUDED** in the informed consent document, the following language should be used **instead**:

If you have questions about the sharing of PHI related to this research study, call ***[Principal Investigator or medical supervisor’s name]*** at ***[insert telephone number]***. If you have questions about your rights as someone taking part in research, you may call the ECU University and Medical Center Institutional Review Board (UMCIRB) at phone number 252-744-2914 (days). ***[for research studies conducted through ECU Health also add “You may also contact the ECU Health Center for Research and Grants at research@ecuhealth.org]*** If you would like to report a complaint or concern about this research study, you may call the Director for Human Research Protections, at 252-744-2914 ***[for research studies conducted through ECU Health add…“and the ECU Health Risk Management Office at 252-413-4473”]***. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at East Carolina University at 252-744-5200 ***[for research studies conducted through ECU Health add…“and the Privacy Officer at ECU Health at 252-847-6545 or email ECUH\_privacy@ecuhealth.org”]***

**REQUIRED LANGUAGE; IF APPLICABLE TO THE STUDY:**

1. **IRS 1099**

It is federally required that participants who receive $600 or more for participating in a research study must be reported to the IRS for tax purposes. The study team is responsible for including language in the consent explaining that participants receiving $100 or more for participating in a research study will be asked to provide their Social Security Number (SSN). ECU has a [Disclosure Statement](https://rede.ecu.edu/umcirb/forms/) that should be utilized for this process. The statement should be added within the consent document but can be submitted as a stand-alone document that will be an appendix to the main study consent document.

1. **Real or Perceived** [**Conflict of Interest**](https://rede.ecu.edu/oric/conflicts-of-interest/)

The consent document must contain a statement where there is a real or perceived conflict of interest on the part of the principal investigator, a sub-investigator, research team staff member or family member of someone on the research team. You may cut and paste the language from the block below. Please customize the statement to your study circumstances ensuring the information matches the Conflict of Interest management plan.

“The ***[principal investigator***, ***sub-investigator, research staff member, or family member]*** has a potential conflict of interest that involves ***[provide a brief description of the conflict])***. ***[ECU, institution’s name or office name]*** and ***[name or title of person with conflict]*** have developed a management plan to reduce any negative impact that would otherwise occur from the potential conflict of interest. This plan has been reviewed by the University & Medical Center Institutional Review Board and found to be adequate to protect your rights.”

**Any consent documents uploaded for IRB review and approval found to be missing any required federal or local elements will be returned to the study team for revision.**